Office Action, on page 4, line 6, where the Examiner is discussing the <u>Porter</u> reference, the Examiner himself uses the term "cooperating" when discussing the effects of the <u>Porter</u> formulation to improve growth. Applicants, therefore, believe that the rejection does not have merits and request withdrawal of the rejection.

....

The Examiner rejected Claims 1-13, 16, 17 and 20 under 35 U.S.C. §102 (b) as being anticipated by <u>Deasy</u> 4,874,612. The <u>Deasy</u> formulation is a multi-component implant which contains at least two shaped *pieces* containing active compound (col. 1, lines 50-52, italics added for emphasis). They are strictly mechanical forms that may or may not contain active compound (col. 2, lines 62-63). When the piece(s) contain the active compound, the ingredients in the pieces are not different; only the shapes and/or their numbers are different. The pieces serve to regulate the release of the medicament into the body. The instant composition, on the other hand, is a dual formulation composition (see the amended Claim 1), and the two formulations are different. While both formulations contain the active compound, the first formulation contains no controlled release agent and the second one contains the controlled release agent. Applicants believe that the amended Claim 1 clarifies this dual formulation approach which is substantially different from the <u>Deasy</u> formulation. Applicants, therefore, believe that there is no anticipation and respectfully request withdrawal of the 102(b) rejection based on the <u>Deasy</u> reference.

The Examiner rejected Claims 1-20 under 35 U.S. §103(a) as being unpatentable over the Deasy reference and Porter GB 2397484 in view of Horykiewytsch 5,252,561 patent. As stated above, the <u>Deasy</u> reference is different from the instant implant composition. <u>Porter</u> does not teach use of anabolic agents. Porter simply teaches a method to implant high density particulates such as copper oxide in the form of rod, filament etc., and zinc oxide, to an animal by using cellulose, lactose or starch as a binding agent. There is no dual formulation, no anabolic agent, no controlled release agent and no loading of two different formulations in an implant device and injecting simultaneously into an animal (as the instant application teaches) to produce growth effects. The Horykiewytsch reference teaches a method to control the release of an implant into the animal's body by using a weighting agent (e.g. iron powder) (col. 1, lines 8-10 and claim 2). The rate of release of the medication in the body is not controlled. The instant patent application, on the other hand, teaches how to control the rate of release of the medication (active ingredient, the anabolic agent in this case) in the body. The two disclosures are quite different. Thus, the Porter reference and the Horykiewytsch reference do not add anything to the Deasy reference to make the instant invention obvious.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious over Lee 2,546,759, presumably modified with the Nessel 3,920,806, and Dunn 5,990,194 references. Each of these references teaches a method to introduce a medicament into an animal's body by applying the medication in a specific device or in a vehicle. There is no teaching of dual formulations and no disclosure anywhere where the rate of release of the medicament inside the animal's body is controlled in such a manner as to regulate the growth of the animal. Only the instant application, by its dual formulation approach, teaches such a method. Applicants, therefore, respectfully request withdrawal of this 103(a) rejection too.

Applicants, therefore, believe that whether used alone or in combination, the references cited by the Examiner do not anticipate or make the invention obvious. There being no other rejection pending, Applicants believe that Claims 1-20 are in allowable condition. Such an action is earnestly requested. If the Examiner has questions, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Dr. Palaiyur S. Kalyanaraman Registration No. 34,634

JAN 10 2001

RECEIVED

TECH CENTER 1600/2900

January 2, 2001 Schering-Plough Corporation Patent Department, K-6-1, 1990 2000 Galloping Hill Road Kenilworth, NJ 07033-0530 Tel: 908-298-5068

Tel: 908-298-5068 Fax: 908-298-5388

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on

January 2, 2001

٠..

Palaiyur S. Kalyanaraman

Registered Representative

Signature and Date of Signature

O I DE LAW O A SERVICE DE LA CONTROL DE LA C